



Updated Guidelines for SARS-CoV-2 Variant Strain Surveillance and Submission

Date: March 26, 2021

Public Health Message Type: ☐ Alert ☐ Advisory ☒ Update ☐ Information

Intended Audience: ☒ All public health partners ☒ Healthcare providers ☒ Infection preventionists
☒ Local health departments ☐ Schools/Childcare centers ☐ ACOs
☐ Animal health professionals ☒ Other: Clinical laboratories

Key Points:

- Multiple variants of the virus that cause COVID-19 have been circulating both in the United States and globally during this pandemic.
- In collaboration with the SARS-CoV-2 Interagency Group (SIG) established by the Department of Health and Human Services (HHS), CDC has developed a classification scheme for variants of SARS-CoV2:
 - Variants of Interest
 - Variants of Concern
 - Variants of High Consequence
- Currently there are no SARS-CoV-2 variants that rise to the level of high consequence, however variant status might escalate or deescalate and further information on each class can be found at: <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html>
- Routine collection of standardized epidemiologic and clinical data from cases as well as linking this data with associated virus sequences, can help characterize clusters of COVID-19 cases and better understand transmissibility, pathogenicity, and re-infection.
- NJDOH requests specimens for sequencing that meet the following criteria, and for which a variant strain is suspected:
 - SARS-CoV-2 -positive specimens (**RT-PCR CT values ≤28** preferred if available) collected within the 7 days prior to shipment AND
 1. Recent travel to and/or from South Africa or Brazil or countries outside the United States that have reported the B.1.351 or the P.1 Sars-CoV-2 variant or close contacts of cases with such travel, OR
 2. Suspected reinfection (recurrence of symptoms) and positive test result ≥90 days after the initial RT-PCR positive test result (not antigen or serology), OR
 3. Cases associated with an outbreak or cluster of concern, OR
 4. Vaccine breakthrough case defined as a U.S. resident who has SARS-CoV-2 RNA or antigen detected on a respiratory specimen collected ≥14 days after completing the primary series of an FDA-authorized COVID-19 vaccine.
Note: NJDOH requests residual post vaccination or acute serum if available on vaccine breakthrough cases.
- This testing is being performed at the Division of Public Health and Environmental Laboratories (PHEL) for epidemiological surveillance purposes; results will not be reported to submitters. Due to limited sequencing capacity, only a subset of the submitted specimens may be sequenced. If a variant of concern is identified, additional guidance will be provided as appropriate.



Action Items:

- To submit specimens meeting criteria #1 and #2, clinicians and laboratory partners can send specimens to PHEL with no prior approval needed.
- For persons meeting criteria #3 and #4 (associated with an outbreak/cluster or suspect vaccine failure), clinicians should consult their local health department. A directory of local health departments is available at www.localhealth.nj.gov.
 - After consultation with clinicians, local health departments can approve specimens for sequencing and should provide the CDRSS Case ID# to the clinician to be included in the “CDS Approval Number” box on the SRD-1 form. The LHD must enter the following information (as applicable) in CDRSS for these cases and email the case IDs to their Communicable Disease Service (CDS) COVID Epidemiologist:
 - Outbreak (E#) or investigation number (I#)
 - Signs/symptoms and hospitalization status
 - Vaccination status (vaccine manufacturer and date of administration)
 - Additional applicable information and note in Comments that the specimen will be sent to PHEL for sequencing
- Providers and laboratories performing sequencing **should report** sequencing results to NJDOH on all variants defined by CDC at <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html> via secure email to CDS.COVIDM@doh.nj.gov or fax to (609) 826-5972. While currently there are no “Variants of high consequence” providers should continue to monitor the variant classification scheme and report any variants that escalate to this class along with new variants that get added to any of the other classes.
- As of March 20, 2021, these variants include:
 - B.1.1.7
 - B.1.351
 - B.1.427
 - B.1.429
 - B.1.525
 - B.1.526
 - P.1 and
 - P.2

How to submit specimens for sequencing to PHEL:

- Refer to the PHEL Technical Bulletin below for general guidance on specimen submission and acceptable specimen types.
- Store respiratory specimens at 2-8°C for up to 72 hours after collection. If a delay in testing or shipping is expected, specimens must be stored at -70°C or below and shipped on dry ice.
 - If samples have been refrigerated for greater than 72 hours after time of collection, consider collecting a new specimen for submission.
 - Samples not on dry ice received more than 72 hours after collection will be rejected.
- For vaccine breakthrough cases please submit specimens for serology in addition to the respiratory specimen:
 - Blood specimens should be collected in clean dry tubes without anticoagulants. The gold top serum separator vacutainer tubes with clot activator/separators are preferred.



- Specimen tubes must have 2 unique identifiers (full patient name, and either a date of birth or unique clinic patient ID #)
- If possible, it is recommended that the blood specimens be centrifuged at 1000 – 1200 x g for 10 ± 5 minutes, within 60 minutes after the clot has formed and prior to refrigeration at 2 - 8° C. If it is not possible, centrifugation will be done at PHEL.

NOTE: Gently invert the tube for 5-10 times to activate the clotting; let stand for 20-30 minutes before centrifuging for 10 minutes. All blood specimens should be stored at 2 - 8° C until transport to PHEL. Testing should be performed within 5 days of collection. If a delay of greater than 5 days is anticipated before arrival, specimen should be frozen at < -20° C.

- Please alert SARS.sequencing@doh.nj.gov upon shipping a specimen for sequencing with the number of samples being shipped, reason for shipping and estimated date/time of delivery.
- For sequencing requests, on the SRD-1 form, check 'other' category and write-in "SARS-CoV-2 RNA Sequencing" for the test requested. For serology requests please check 100030/SARS-CoV2 IgG and 10040/ SARS-CoV2 IgM under Viral Serology Screens (SRD-1 form available [here](#))
 - Include information related to sequencing approval criteria (#1-4 above) in the Pertinent Clinical Information box on the SRD-1 form. If the sequencing criteria are not indicated on the submission form, the sample may not be considered for sequencing.

References and Resources:

- <https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant.html> (CDC guidance)
- <https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant-cases.html> (Variant Cases)
- <https://www.nj.gov/health/phel/documents/Bulletins/Supplemental%20Bulletin%2020.1.5%20SARS-CoV-2%20Testing%20at%20PHEL%20V5.pdf> (NJPHL specimen submission guidance)